Exhibit E

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to Plaintiffs' Motion for Partial Summary Judgment

Effective: August 16, 2004 to August 23, 2007

West's Annotated California Codes
Welfare and Institutions Code
Division 9. Public Social Services
Part 3. Aid and Medical Assistance
Chapter 7. Basic Health Care
Article 3. Administration

➡ § 14105.45. Definitions; reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs; average sales price information

(a) For purposes of this section, the following definitions shall apply:

(1) “Average sales price” means, of a drug or biological, the sales price for a National Drug Code for a calendar quarter for a manufacturer for a unit, calculated as follows:

(A) The manufacturer's sales to all purchasers, excluding sales exempt under subparagraph (B), of a drug or biological in the United States in the calendar quarter, divided by the total number of the units of that drug or biological sold by the manufacturer in that calendar quarter.

(B) In calculating the manufacturer's average sales price, the following sales shall be excluded:

(i) Sales exempt from inclusion in the determination of “best price” under Section 1927(c)(1)(C)(i) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(1)(C)(i)).

(ii) Any other sales as the Secretary of the United States Department of Health and Human Services identifies as sales to an entity that are merely nominal in amount, as applied for purposes of Section 1927(c)(1)(C)(ii)(III) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(1)(C)(ii)(III)), except as the secretary may otherwise provide.

(C) In calculating the manufacturer's average sales price, the price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates, other than rebates under Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8). After 2004, the secretary may include in the manufacturer's average sales price other price concessions, which may be based on recommendations of the Inspector General of the United States Department of Health and Human Services, that would result in a reduction of the cost to the purchaser.

(D) In the case of a drug or biological during an initial period, not to exceed a full calendar quarter, in which

data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the department may determine the amount payable under this section for the drug or biological based on the wholesale selling price.

(2) “Average wholesale price” means the price for a drug product listed in the department's primary price reference source.

(3) “Direct price” means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source.

(4) “Estimated acquisition cost” means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(5) “Federal upper limit” means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) “Generically equivalent drugs” means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

(7) “Legend drug” means any drug whose labeling states “Caution: Federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.

(8) “Maximum allowable ingredient cost” (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

(9) “Innovator multiple source drug,” “noninnovator multiple source drug,” and “single source drug” have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

(10) “Nonlegend drug” means any drug whose labeling does not contain the statement referenced in paragraph (7).

(11) “Wholesale selling price” means the weighted (by unit volume) mean price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor.

(12) “Selling price” means the price used in the establishment of the estimated acquisition cost. The department shall base the selling price on the average sales price reported by manufacturers pursuant to subdivision (c). The

selling price shall not be considered confidential and shall be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(b)(1) Reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall consist of the estimated acquisition cost of the drug plus a professional fee for dispensing. The professional fee shall be seven dollars and twenty-five cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars ($8) per dispensed prescription. For purposes of this paragraph “skilled nursing facility” and “intermediate care facility” shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

(2) The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows:

(A) For single source and innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.

(B) For noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.

(C) The department shall not use the direct price paid by pharmacies to drug manufacturers to establish estimated acquisition cost.

(3) For purposes of paragraph (2), the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department.

(B) The department shall notify each selected wholesale drug distributor, in writing, that the wholesale drug distributor has been identified as a source of wholesale selling price information.

(C) Wholesale drug distributors notified pursuant to subparagraph (B) shall, no later than 30 days after the end of each month, and in a format determined by the department, provide to the department the wholesale selling price of all legend and nonlegend drugs sold to pharmacies.

(D) The department shall update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

(E) The failure of a wholesaler to report wholesale selling prices pursuant to subparagraph (C) of paragraph (3) of subdivision (b) shall result in the director denying payment for all drugs supplied by that wholesaler to Medi-Cal program beneficiaries. The denial of payment shall be effective no sooner than 30 days after notifying pharmacy providers of the change through a provider bulletin.

(F) All pricing information reported by a wholesale distributor to the department pursuant to this section shall be considered confidential and corporate proprietary information and shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(c)(1) Manufacturers and principal labelers of legend and nonlegend drugs shall, no later than 30 days after the end of each calendar quarter, and in a format determined by the department, provide to the department the average sales price of each of the manufacturer's legend and nonlegend drugs.

(2) The department shall update the Medi-Cal claims processing system to reflect the selling price of drugs not later than 62 calendar days after the end of each calendar quarter.

(3) For manufacturers that fail to provide average selling price information pursuant to this section, the department may subject their drugs' availability to prior authorization. The provisions of this subdivision shall be included in contracts or contract amendments entered into by the department pursuant to Section 14105.3, 14105.33, 14105.37, or 14105.39, and manufacturers shall continue rebate payments according to the rebate provisions in the contracts. Nothing in this paragraph shall affect a Medi-Cal beneficiary's ability to receive continuity of care for 60 days as contained in subdivision (i) of Section 14105.33.

(4) All pricing information reported by manufacturers and principal labelers of legend and nonlegend drugs to the department pursuant to this section shall be considered confidential and corporate proprietary information and shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.

(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

CREDIT(S)

(Added by Stats.2004, c. 228 (S.B.1103), § 17, eff. Aug. 16, 2004.)

HISTORICAL AND STATUTORY NOTES2009 Electronic Update1CAQ2004 LegislationFor legislative findings, declarations, and intent, cost reimbursement provisions, and urgency effective provisions relating to Stats.2004, c. 228 (S.B.1103), see Historical and Statutory Notes under Corporations Code § 17002.Former §

14105.45, added by Stats.1990, c. 456 (A.B.3573), § 25.5, eff. July 31, 1990, amended by Stats.1990, c. 457 (S.B.2097), § 17, eff. July 31, 1990; Stats.1990, c. 1643 (A.B.4195), § 6, eff. Sept. 30, 1990; Stats.2002, c. 1161 (A.B.442), § 72, eff. Sept. 30, 2002, relating to maximum allowable ingredient costs for drugs, was repealed by Stats.2004, c. 228 (S.B.1103), § 16, eff. Aug. 16, 2004.Derivation: Former § 14105.46, added by Stats.2002, c. 1161 (A.B.442), § 73.UNITED STATES CODE ANNOTATEDMedical assistance, multiple source drugs, upper payment limits, see42 U.S.C.A. § 1396r-8.West's Ann. Cal. Welf. & Inst. Code § 14105.45, CA WEL & INST § 14105.45

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